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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,884	03/21/2001	Russell John Mumper	NANO:003US	1135

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,884

Applicant(s)

MUMPER ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,23-29,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,23-29,33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 5/15/06.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 21,23-29,33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been amended to include a limitation that excludes aqueous dilution while the disclosure in the specification does not rule out such limitations. The Specification recites no dilution or undiluted products and not a step explicitly excluding aqueous dilutions since dilutions can be done with any other known solvent for the material. For these reasons at least the amended claims represent new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21,23-29,33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. The term "dilution" in claim 21 is a relative term which renders the claim indefinite. The term "dilution" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There are no indications of a starting concentration representative of an undiluted solution leaving the claim unclear as to what constitutes a dilution of the instant invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21,23,25,27, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Gasco, M. R. (*Solid Lipid Nanospheres from warm Micro-Emulsions*; **Pharmaceutical Technology Europe**, vol. 9, no. 11, 1997. XP009030038 hereafter '038). The claims are drawn to a method of making a solid nanoparticle comprising making an oil-in-water microemulsion by melting a solid lipid material and adding a molecule of interest, then cooling the composition. The resultant nanoparticles are below 300 nm.

3. The '038 reference teaches the production of solid lipid nanoparticles (abstract). The solid lipid nanoparticles are the product of warmed micro-emulsions (*Ibid.*). First a fatty acid is melted, next a mixture of co-surfactant, water and surfactant are warmed and mixed into the melted fatty acid. Under mild mixing, the aqueous phase is added to the melted lipophilic phase

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and clear system is formed. The mixture is then cooled and mildly mixed (page 53, column 2 and 3). The process operates in temperature ranges from 50-70 degrees Celsius, enough to melt the lipid, but not destroy the drug molecules (page 54-57). The surfactants include polysorbates such as such a Tween 20 (page 54). The resulting nanoparticles are 50-75 nm in diameter (page 54). Peptides can also be incorporated in to the nanoparticles (page 57, column 3). The solid lipid nanoparticles can be used for different drug administration routes including oral, ocular and parenteral (page 58, col. 1). These disclosures render the instant claims anticipated.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 24,26,28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Gasco, M. R. (*Solid Lipid Nanospheres from warm Micro-Emulsions*;

Pharmaceutical Technology Europe, vol. 9, no. 11, 1997. XP009030038 hereafter '038). The

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claims are drawn to a method of making a solid nanoparticle comprising making an oil-in-water microemulsion by melting a solid lipid material and adding a molecule of interest, then cooling the composition. The resultant nanoparticles are below 300 nm.

7. As discussed above the '038 reference teaches the production of nanoparticles from warmed micro-emulsions. The reference however differs by not reciting the specific concentrations recited in the claims. However it is the position of the Examiner that such limitations do not impart patentability on the claims. The general conditions of the claims have been met by the reference. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

8. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic or pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

9. With these things in mind, it would have been obvious to follow the suggestions of the '038 reference in order to produce stable nanoparticle compositions. It would have been obvious to follow these suggestions with an expected result of a stable nanoparticle formulation, produced in an efficient inexpensive manner.

Response to Arguments

10. Applicant's arguments with respect to claims 21,23-29,33 and 34 have been considered but are moot in view of the new ground(s) of rejection. Due to the new matter rejection, it remains the position of the Examiner that the Gasco reference continues to anticipate and obviate the instant invention. The Gasco reference teaches a method of making nanoparticles, comprising making an oil-in-water microemulsion, heating the microemulsion and cooling the resultant to form nanoparticles. The reference teaches the same nanoparticle matrix materials and surfactants as the instant claims. The claims remain anticipated and obviated.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER